

REMARKS

Claims 1-6, 12, 15, 16, 43, 47, 48, 59-61, 140-146 and 174-176 are pending in this application. Claims 140-146 and 174-176 are withdrawn by the examiner. Claims 1-6, 12, 15, 16, 43, 47, 48, and 59-61 are currently under examination. Applicants amend the independent claims 1, 43, and 59, for clarity, to recite "a) compression molding of polyethylene powder to a another piece, thereby forming an interlocked hybrid material having an interface between the compression molded polyethylene and the piece; b) irradiating crosslinking the compression molded polyethylene portion of the hybrid material by ionizing radiation...." Amendments to the claims are fully supported by the specification; see for example, for example, pages 4-6; Examples 1 and 5; original claims 36, 59, 68, 94 and 114. Claim 60 is amended for clarity to recite "a piece" instead of "another piece". Therefore, no new matter is introduced. The Office Action is discussed below:

Withdrawal of Indefiniteness Rejection:

Applicants thank the examiner for withdrawal of the rejection of claims 6 and 48 in view of the response and amendment filed on October 23, 2008.

Obviousness Rejections:

On pages 2-9 of the Office Action, the examiner has maintained the obviousness rejections of the claims as discussed below:

On pages 2-5 of the Office Action, the examiner rejects Claims 1-4, 6, 12, 15, 16, and 59-61 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472).

On pages 5-6 of the Office Action, the examiner rejects Claims 43 and 48 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) and Johnson (PN 4971761).

On page 6 of the Office Action, the examiner rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in

view of Ashby *et al.* (PN 5989472) as applied to claim 1 above, and further in view of Kagiya *et al.* (PN 3894928).

On page 7 of the Office Action, the examiner also rejects Claim 5 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) as applied to claim 1 above, and further in view of Patel (PN 4164458).

On pages 7-8 of the Office Action, the examiner rejects Claim 47 under 35 U.S.C. 103(a) allegedly as being unpatentable over Merrill *et al.* (PN 5879400) in view of Ashby *et al.* (PN 5989472) and Johnson (PN 4971761) as applied to claim 43 above, and further in view of Patel (PN 4164458).

Applicants respectfully disagree with the examiner and submit that the examiner has not addressed how any combination of the cited references teach or suggest: i) crosslinking by ionizing radiation the compression molded polyethylene portion of a hybrid material having an interface between the compression molded polyethylene and a piece; or ii) heating of an irradiation crosslinked hybrid material above the melting point of the crosslinked polyethylene, wherein the crosslinked hybrid material having an interface between the compression molded polyethylene and a piece. Applicants are not just combining a previously heated and/or crosslinked polyethylene with a piece.

The examiner also has not addressed how any combination of the cited references teach or suggest a medical implant obtained by a method that involve: i) crosslinking by ionizing radiation the compression molded polyethylene portion of a hybrid material having an interface between the compression molded polyethylene and a piece; or ii) heating of an irradiation crosslinked hybrid material above the melting point of the crosslinked polyethylene, wherein the crosslinked hybrid material having an interface between the compression molded polyethylene and a piece.

The examiner also has not addressed how any combination of the cited references teach or suggest a medical implant containing interlocked hybrid

material having an interface between a compression molded polyethylene and a piece, or a method of making such medical implant, wherein the method involves: i) crosslinking by ionizing radiation the compression molded polyethylene portion of a hybrid material having an interface between the compression molded polyethylene and a piece (that is, irradiation after compression molding); or ii) heating a hybrid material having an interface between a crosslinked polyethylene and a piece (that is, heating of a compression molded hybrid material above the melting point of the crosslinked polyethylene).

Clearly, a combination of Ashby and Merrill or any other cited references does not teach crosslinking or heating above the melt once a hybrid material is produced.

Applicants reiterate and refer to the dictates of the MPEP that:

"MERE STATEMENT THAT THE CLAIMED INVENTION IS WITHIN THE CAPABILITIES OF ONE OF ORDINARY SKILL IN THE ART IS NOT SUFFICIENT BY ITSELF TO ESTABLISH *PRIMA FACIE* OBVIOUSNESS

A statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art" at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is not sufficient to establish a *prima facie* case of obviousness without some objective reason to combine the teachings of the references. *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). "[R]ejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR*, 550 U.S. at ___, 82 USPQ2d at 1396 quoting *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006)."

See MPEP § 2143.01 (IV) at 2100-140 (Rev. 6, September 2007).

In this case, it is discussed in the specification that Merrill *et al.* provides methods for making irradiation of polymeric material (see specification, paragraph bridging pages 1 and 2, for example). In contrast, the invention provides new and improved methods for making and sterilizing medical implants

containing crosslinked polyethylene that is in contact with a piece and forming interfaces. It is not just a combination of two types of materials, as speculated by the examiner, as discussed above. Since the results of irradiation of a medical implant having interfaces (such as a hybrid material) would not have been predictable to one of ordinary skill in the art, mere combination of irradiating polymeric material and adding a metal piece to the irradiated polymeric material would not make the claimed method obvious.

Applicants further refer to the specification (see for example, pages 4-6, Examples 1 and 5), where polyethylene powder and the like materials are compression molded to a metal piece having mesh or porous structure to form a hybrid material having an interface. The hybrid material is subsequently radiation crosslinked and heated above the melting point of the crosslinked hybrid materials. The radiation crosslinks the polyethylene portion of the hybrid material.

First, none of the cited references teach or suggest compression molding of polyethylene powder to a piece, and second, none teach or suggest irradiation and subsequent heating of the hybrid medical implant.

Finally, even if the cited references are combined by hypothetical skilled person, such a combination would not result into a method of making a medical implant by irradiating and heating the medical implant having an interface. In this context, applicants reiterate, the applied references must teach or suggest all claim limitations. Applicants submit that the rejections do not meet this test and refer the examiner that:

"All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

See, MPEP § 2143.03 at 2100-142 (Rev. 6, September 2007).

Applicants point out that any combination of Ashby, Merrill, Johnson,

Kagiya, and/or Patel would not provide the claimed methods nor the resulting claimed medical implant containing crosslinked polyethylene that is in contact with a piece and forming interfaces. Because, none of the cited references, or any combination thereof, teach or suggest: a) compression molding of polyethylene powder to a piece, thereby forming an interlocked hybrid material having an interface between the compression molded polyethylene and the piece; b) crosslinking the compression molded polyethylene portion of the hybrid material by ionizing radiation; and c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene.

Accordingly, any combination of the cited reference would not teach or suggest all claim limitations of the independent claims 1, 43 or 59. Thus, all independent claims and the claims depending therefrom are nonobvious over the cited references, as mandated in the MPEP, and as clarified above.

In order to further distinguish the claimed invention and for additional clarity, applicants amend the independent claims 1, 43, and 59 to recite: "a) compression molding of polyethylene powder to a another piece, thereby forming an interlocked hybrid material having an interface between the compression molded polyethylene and the piece;

b) irradiating crosslinking the compression molded polyethylene portion of the hybrid material by ionizing radiation...."

Again, applicants reiterate, the combination of Ashby, Merrill, Johnson, Kagiya, and/or Patel is nowhere supported by the references or in the common knowledge of the art. Accordingly, the rejection calls to mind the Federal Circuit decision of *In re Rouffet*, 149 F.3d 1350 (Fed. Cir. 1998), where the court explained:

As this court stated, "virtually all [inventions] are combinations of old elements." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 698, 218 USPQ 865, 870 (Fed. Cir. 1983); *see also Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1579-80, 219 USPQ 8, 12 (Fed. Cir. 1983) ("Most, if not all, inventions are combinations and mostly of old elements").

Therefore an examiner may often find every element of a claimed invention in the prior art. If identification of each claimed element in the prior art were sufficient to negate patentability, very few patents would ever issue. Furthermore, rejecting patents solely by finding prior art corollaries for the claimed elements would permit an examiner to use the claimed invention itself as a blueprint to defeat the patentability of the claimed invention. Such an approach would be an "illogical and inappropriate process by which to determine patentability." *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ2d 1551, 1554 (Fed. Cir. 1996).

To prevent the use of hindsight based on the invention to defeat patentability of the invention, this court requires the examiner to show motivation to combine the references that create the case of obviousness. In other words, the examiner must show reasons that the skilled artisan, confronted with the same problems as the inventors and with no knowledge of the claimed invention, would select the elements from the cited prior art references for combination in the manner claimed.

In re Rouffet, 149 F.3d 1350, 1357 (Fed. Cir. 1998).


Thus, the rejection does not satisfy the strictures of the *Rouffet* decision. The references are not combinable without proscribed hindsight, that is, for example, the method steps of: a) compression molding of polyethylene powder to a piece, thereby forming an interlocked hybrid material having an interface between the compression molded polyethylene and the piece; b) crosslinking the compression molded polyethylene portion of the hybrid material by ionizing radiation; and c) reducing free radicals in the crosslinked polyethylene by heating the hybrid material above the melting point of the crosslinked polyethylene, as discussed above, would be based on the knowledge gleaned only from the instant disclosure. Such a reconstruction is clearly improper. *In re McLaughlin* 443 F.2d 1392, 1395, 170 USPQ 209, 212 (CCPA 1971).

Therefore, withdrawal of the obviousness rejection is solicited.

REQUEST

Applicants submit that claims 1-6, 12, 15, 16, 43, 47, 48, and 59-61 are in condition for allowance and request consideration to that effect. The examiner is invited to contact the undersigned at (202) 416-6800 should there be any questions.

Respectfully submitted,



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Date

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